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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,850	09/22/2006	Philippe Moser	C 2939 PCT/US	4436

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FOX ROTHSCHILD LLP
2000 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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07/31/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 10/593,850	Applicant(s) MOSER ET AL.	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0906</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of the election of species of Group C (i.e. drawn to providing anti-ageing and/or anti-wrinkle and/or revitalizing/rejuvenating and/or repair and/or appealing and/or anti-irradiation and/or antioxidant and/or radiation protection effects on the skin) in the reply filed on 04/30/2009 is acknowledged.

Claims 1-20 have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a composition and/or method comprising an extract of a plant belonging to the species *Buchholzia coriacea* and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders, the specification does not enable any person in the art for preparing a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state

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of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders.

Applicant has reasonably demonstrated on pages 28-37 within the examples 1-8 of the specification a composition and/or method comprising an extract of a plant belonging to the species *Buchholzia coriacea* and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders.

Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders. For example, Ajaiyeoba teaches a composition and/or method comprising an extract of a plant only belonging to the species *Buchholzia coriacea* having an antimicrobial properties to be administered to a patient in need thereof for the

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treatment of skin disorders (see, e.g. Anti-microbial and cytotoxicity evaluation of *Buchholzia coriacea* stem bark, Fitoterapia 74 (2003) pages 706-709). Thus, the art is silent regarding the efficacy of a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders. Therefore, applicant's claimed composition and/or method is unpredictable in the art.

Furthermore, applicant's specification has reasonably demonstrated on pages 28-37 within the examples 1-8 of the specification a composition and/or method comprising an extract of a plant belonging to the species *Buchholzia coriacea* and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein to be administered to a patient in need thereof for the treatment of skin disorders. Therefore, it would require undue experimentation by one of skill in the art to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-11 and 17 are rejected under 35 USC 102(e) as being anticipated by Ajaiyeoba et al. (*Anti-microbial and cytotoxicity evaluation of Buchholzia coriacea stem bark*, Fitoterapia 74 (received 18 March 2003; accepted in revised form 29 May 2003), pages 706-709).

Applicant claims a method for the cosmetic treatment of the skin (i.e. a skin disorder such as skin inflammation) comprising the steps of administering to a patient in need thereof a composition comprising an effective amount of the plant extract from a plant belonging to the entire *Buchholzia* genus.

Ajaiyeoba anticipates the claimed invention because Ajaiyeoba teaches a method for the cosmetic treatment of the skin (i.e. a skin disorder such as smallpox sores) comprising the steps of administering to a patient in need thereof a composition comprising an effective amount of the plant extract from a plant belonging to the species *Buchholzia coriacea* having antimicrobial properties whereas when the same *Buchholzia coriacea* species as the claimed invention is administered to a subject to treat the skin (i.e. to treat skin disorder such as smallpox sores), it would intrinsically have the claimed functional effect as the claimed invention's functional effect (i.e. the functional effect of treating skin inflammation whereas smallpox sores are well known to cause skin inflammation) (see, e.g. entire document). Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 USC 103(a) as being unpatentable over Ajaiyeoba et al. (*Anti-microbial and cytotoxicity evaluation of Buchholzia coriacea stem bark*, Fitoterpia 74 (received 18 March 2003; accepted in revised form 29 May 2003), pages 706-709) in view of Fawzi (US 4343798).

Applicant claims a composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus and other claimed active ingredients therein (i.e. an additional additive and/or auxiliary) to be administered (i.e. orally or topically in claimed forms) in effective amounts to a patient in need thereof for the treatment of skin disorders (i.e. a skin disorder such as skin inflammation).

Ajaiyeoba teaches a composition and/or method for the cosmetic treatment of the skin (i.e. a skin disorder such as smallpox sores) comprising the steps of administering to a patient in need thereof a composition comprising an effective amount of the plant extract from a plant belong to the species *Buchholzia coriacea* (the stem bark of the species of *Buccholzia coriacea*) having antimicrobial properties whereas when the same *Buchholzia coriacea* species as the claimed invention is administered to a subject to treat the skin (i.e. to treat skin disorder such as smallpox sores), it would intrinsically

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have the claimed functional effect as the claimed invention's functional effect (i.e. the functional effect of repairing skin disorders and/or treating skin inflammation whereas smallpox sores are well known to cause skin inflammation) (see, e.g. entire document). Ajaiyeoba, however, does not teach within its composition and/or method the other claimed active ingredients therein (i.e. an additional additive and/or auxiliary such as an antimicrobial agent) to be administered in effective amounts to a patient in need thereof for the treatment of skin disorders.

Fawzi beneficially teaches that antimicrobial agents are useful within compositions for the treatment of skin disorders (see, e.g. entire patent especially column 1 lines 15-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ajaiyeoba's composition and/or method to include other and/or an additional active ingredient such as an antimicrobial agent as taught by Fawzi because the above combined cited references as a whole would create the claimed composition and/or method comprising an extract of a plant belonging to the entire *Buchholzia* genus (i.e. the species of *Buchholzia coriacea*) and other claimed active ingredients therein (i.e. an additional additive and/or auxiliary such as antimicrobial agents) to be administered in effective amounts to a patient in need thereof for the treatment of skin disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (e.g. the species *Buchhozia coriacea* having antimicrobial properties with an additional antimicrobial agent to treat skin disorders), in

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order to form a third composition to used for the same purpose". The adjustments of other conventional working conditions (i.e. determining suitable amounts/ranges of each active ingredient within the claimed composition, the substitution of one form for another and the substitution of one form of administration for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655